

PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Complete if Known Substitute for form 1449A/PTO 10/070.093 **Application Number** INFORMATION DISCLOSURE 02/27/2002 Filing Date First Named Inventor STATEMENT BY APPLICANT P. York et al Art Unit (use as many sheets as necessary) Unassigned Examiner Name Attorney Docket Number 0113.00 of Sheet

	U.S. PATENT DOCUMENTS						
Examiner		Document Number Number - Kind Code 2 (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear		
W	AA	US-4,328,107	05/04/1982	Wright			
_	AB	US-4.361,285	11/30/1982	Koppehele et al.			
	AC	US-4.582.731	04/15/1986	Smith			
	AD	US-4,702.799	10/27/1987	Tuot			
	AE	US-4.737.384	04/12/1988	Murthy et al.			
	AF	US-4.919.853	04/24/1990	Alvarez et al.			
	AG	US-4.923.720	05/08/1990	Lee et al.	<u> </u>		
	AH	US- 4.970.093	11/13/1990	Sievers et al.	<u> </u>		
	ΑĪ	US- 4,977.785	12/18/1990	Willoughby et al.	<u> </u>		
	AJ	US- 5,009,367	04/23/1991	Nielsen			
	AK	US-5.043,280	08/27/1991	Fischer et al.			
	AL	US- 5.106.659	04/21/1992	Hastings et al.			
	AM	US- 5,221,731	06/22/1993	Weymans et al.			
	AN	US- 5,229,486	07/20/1993	Paul et al.	<u> </u>		
	AO	US- 5.437,798	08/01/1995	LaRoche et al.			
7	AP	US- 5,548,004	08/20/1996	Mandel et al.			
1,	AQ	US- 5.554,382	09/10/1996	Castor			
	AR	US- 5.639,441	06/17/1997	Sievers et al.			
V	AS	US- 5.707.634	01/13/1998	Schmitt	<u> </u>		
7100	AT	US- 5.708.039	01/13/1998	Daly et al.			

	FOREIGN PATENT DOCUMENTS									
Examiner			oreion Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages	_			
Initiats:	No.1	Country Code 3	-Number4 -Kind Code4 (if known)	MM-DD-YYYY	Applicant or Glad Gooding.	or Relevant Figures Appear	T6			
(4)	AX	DE	4041563	06/25/1992	Schwarz Pharma AG		╙			
	ΑY	DE	1078283	03/24/1960	F. Aktiengesellschaft	<u> </u>	<u> </u>			
	AZ	EP	0322687	05/05/1993	W. Fischer		<u> </u>			
	BA		0542314	05/19/1993	P. Debenedetti		<u> </u>			
	BB		1-176437	07/12/1989	T. Tauchi		<u> </u>			
	BC	JP	5-57166	03/09/1993	K. Kitagawa					
	_	wo	90/11139	10/04/1990	K. Nielsen		_			
W		wo	90/03782	04/19/1990	W. Schmitt		_			
	CP	GB	2322326	08/26/1998	Bradford Particle					
7.12	CO	wo	95/21688	08/17/1995	W. Eckhard et al.		1_			

Examiner 706 Considered Signature

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ²See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTO/SB/08A (10-01) Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE
STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 2 of 6 Attorney Docket Number 0113.00

			U.S. PAT	ENT DOCUMENTS				
Evaminor	Examiner Cite Document Number Publication Date Name of Patentee or Relevant Passages of Relevant							
Initials*		Number - Kind Code ² (if known	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear			
	ΑU	US-5.716.558	02/10/1998	Nielsen et al.				
GL27	ΑV	US-5.981.474	11/09/1999	Manning et al.				
(XXX	AW	US-6.063,910	05/16/2000	Debenedetti et al.				
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						
		US-						

FOREIGN PATENT DOCUMENTS								
Examiner	Cite No.1	Foreign Patent Document Country Code 3 -Number 4 - Kind Code 5 (Il known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	Т6		
/	WO 95/01221	01/12/1995	Univ. Bradford	or records regards repeat	Ė			
97577	cs	WO 96/00610	01/11/1996	Univ. Bradford				
						-		
	-					⊢		
	\vdash					-		

Examiner Signature	ofuso	Date Considered	MK-06

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Applicant's unique citation designation number (optional). *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. *See Kinds Codes of USPTO Patent Documents at www.u

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

+



PTO/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute to	r form 14498/PTO			Complete if Known		
		210	01 001105	Application Number	10/070.093	
INFOR	RMAHON	บเร	CLOSURE	Filing Date	02/27/2002	
STAT	EMENT B	ν Δι	PPLICANT	First Named Inventor	P. York et al.	
ואופן			LIOAIII	Group Art Unit		
	(use as many sh	eets as	necessary)	Examiner Name	Unassigned	
Sheet	3	of	6	Attorney Docket Number	0113.00	

•	OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS							
Examiner Cite		Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.						
Who have	BF	DEBENEDETTI ET AL., "Application of Supercritical Fluids for the Production of Sustained Delivery Devices," J. Cont. Rel, No. 24, p. 27-44 (1993).						
	ВG	DIXON ET AL., "Polymeric Materials Formed by Precipitation with a Compressed Fluid Antisolvent." A1ChE J., Vol. 39 (No. 1), p. 127-139 (1993).						
	вн	TOM ET AL., "Applications of Supercritical Fluids in the Controlled Release of Drugs," ACS Symposium Series, Supercritical Fluid Engineering Science Fundamentals and Applications, Chpt. 19, p. 238-257 (1993).						
	BI	LARSON ET AL., "Evaluation of Supercritical Fluid Extraction in the Pharmaceutical Industry," Biotech. Progress, Vol. 2 (No. 2), p. 73-82 (1986).						
	ВЈ	Ullmans Encyclopedia of Industrial Chemistry, Vol. B2, Fifth Ed., title page, copyright page, and p. 7-21 and 7-22 (1988).						
	ВK	TOM ET AL., "Particle Formation with Supercritical Fluids - A Review," J. Aerosol Sci., 1st Ed. Vol. 22 (No. 5), p. 555-584 (1981).						
	BL	DEBENEDETTI ET AL., "Rapid Expansion of Supercritical Solutions (RESS): Fundamentals and Applications," Fluid Phase Equilibria, Vol. 82, p. 311-321 (1993).						
	ВМ	GALLAGHER ET AL., "Gas AntiSolvent Recrystallization: New Process to Recrystallize Compounds Insoluble in Supercritical Fluids," ACS Symp. Ser No. 406, p. 334-354 (1989)						
	BN	LAHIERE ET AL., "Mass-Transfer Efficiencies of Column Contactors in Supercritical Extraction Service." Ind. Eng. Chem. Res. No. 26. p. 2086-2092 (1987).						
	во	STAHL ET AL., "Dense Gas Extraction on a Laboratory Scale: A Survey of Some Recent Results." Fluid Phase Equilibria. No. 10, p. 269-278 (1983).						
		DILL ET AL., "Denatured States of Proteins," Annu. Rev. Biochem, No. 60, p. 795-825 (1991).						

	<u> </u>		
Examiner Signature	n/rem	Date Considered	M6-06

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.



PTO/SB/088 (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute to	r form 1449B/PTO			Complete if Known		
		D 100		Application Number	10/070.093	
INFOR	RMATION	DISC	LOSURE	Filing Date	02/27/2002	
CTAT	EMENT R	VAD	PLICANT	First Named Inventor	P. York et al.	
SIAII	FIAIFIA1 D	ı Ar	LIOAITI	Group Art Unit		
	(use as many si	heets as r	ecessary)	Examiner Name	Unassigned	
Sheet	4	of	6	Attorney Docket Number	0113.00	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS							
Examine Initials*	er Cite		T²				
ATS.	B	O'CALLAGHAN ET AL "Novel Method for Detection of (B)-Lactamases by Using a Chromogenic Cephalosporin Substrate." Antimicrobial Agents and Chemotherapy, Vol. 1 (No. 4), p. 283-288 (1972).					
)	ВІ	JUNG ET AL., "Particle Design Using Supercritical Fluids: Literature and Patent Survey," J. of Supercritical Fulids, Vol. 20, p. 179-219 (2001).					
	B	BLEICH ET AL., "Aerosol Solvent Extraction System - A New Microparticle Production Technique," International J. of Pharmaceutics, Vol. 97, p. 111-117 (1993).					
	B	CHANG ET AL, "Separation of B-Carotene Mixtures Precipitated from Liquid Solvents with High-Pressure CO2." Biotechnol. Prog., No. 7, p. 275-278 (1991).					
	Ві	GALLAGHER ET AL., "Gas Anti-Solvent Recrystallization of RDX: Formation of Ultra-fine Particles J of a Difficult-to-Comminute Explosive," The J. of Supercritical Fluids, No. 5, p. 130-142 (1992).					
	В	MATSON ET AL., "Production of Powders and Films by the Rapid Expansion of Supercritical Solutions." J. of Materials Science, No. 22, p. 1919-1928 (1987).					
	В	MOHAMED ET AL., "Solids Formation After the Expansion of Supercritical Mixtures," Supercritical Fluid Science and Technology, Chapter 23, American Chemical Society, p. 355-378 V (1989).					
	B	BARJ ET AL, "Submicronic MgAI2O4 Powder Synthesis in Supercritical KEthanol," J. of Materials Sci., No. 27, p. 2187-2192 (1992).					
	В	CHHOR ET AL., "Synthesis of Submicron TIO2 Powders in Vapor, Liquid and Supercritical Phases, a Comparative Study," Materials Chemistry and Physics, Vol. 32, p. 249-254 (1992).					
V	B	FRANCIS, "Ternary Systems of Liquid Carbon Dioxide," J. of Physical Chemistry, Vol. 58, p. 1099-1114 (1954).					
6/98		YEO ET AL., "Formation of Microparticulate Protein Powders Using a Supercritical Fluid Antisolvent," Biotechnology and Bioengineering, Vol. 41, p. 4341-346 (1993).					

Examiner Signature	the	Date Considered	1-18-0G

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



PTC/SE/08B (10-01)
Approved for use through 10/31/2002, OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute to	r form 1449B/PTO			Complete If Known		
		010	OLOGUEE	Application Number	10/070.093	
INFOR	RIMATION	DIS	CLOSURE	Filing Date	02/27/2002	
STAT	EMENT R	VΔ	PPI ICANT	First Named Inventor	P. York et al.	
STATEMENT BY APPLICANT				Group Art Unit		
	(use as many st	neets a	s necessary)	Examiner Name	Unassigned	
Sheet	5	of	6	Attorney Docket Number	0113.00	

L			OTHER PRIOR ART NON PATENT LITERATURE DOCUMENTS	
	Examiner Initials	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	4	СВ	RANDOLPH ET AL., "Sub-Micrometer-Sized Biodegradable Particles of Poly (L-Lactic Acid) via the Gas Antisolvent Spray Precipitation Process," Biotechnol. Prog, Vol. 9, No. 4, p. 429-435 (1993).	
	1	CC	DEBENEDETTI ET AL., "Supercritical Fluids: A New Medium for the Formation of Particles of Biomedical Interest," Proceed. Intern. Symp. Control Rel. Bioact. Mater., 20, p. 141-142 (1993).	
		CD	DONSI ET AL., "Micronization by Means of Supercritical Fluids: Possibility of Application to Pharmaceutical Field." Pharm. ACTA HELV. 66, Nr. 5-6, p. 170-173 (1991).	
		CE	CYGNAROWICZ ET AL., "Design and Control of a Process to Extract B-Carotene with Supercritical Carbon Dioxide," Biotechnol. Prog. Vol. 6, p. 82-91 (1990).	
		CF	CHEN ET AL., "Supercritical Antisolvnet Fractionation of Polyethylene Simulated with Multistage Algorithm and SAFTEquation of State: Staging Leads to High Selectivity Enhacements for Light Fractions," Ind. Eng. Chem. Res., Vol. 33, p. 306-310 (1994).	
		CG	LOTH ET AL., "Properites and Dissolution of Drugs Micronized by Crystallization from Supercritical Gases." International J. of Pharmaceuticals, Vol. 32, p. 265-267 (1986).	
		СН	BODMEIER ET AL., "Polymeric Microspheres Prepared by Spraying Into Compressed Carbon Dioxide," Pharmaceutical Research, Vol. 12, No. 8, p. 1211-1217 (1995).	
L		CI	TOM ET AL., "Formation of Bioerodible Polymeric Microspheres and Microparticles by Rapid Expansion of Supercritical Solutions," Biotechnol. Prog., Vol. 7, p. 403-411 (1991).	
		CJ	SANCHEZ ET AL., "Development of Biodegradable Microspheres and Nanospheres for the Controlled Release of Cyclosporin A." International J. of Pharmaceutics. Vol. 99, p. 263-273 (1993).	
	Y	CK	JULIENNE ET AL "Preparation of Poly (D, L-Lactide/Glycolide) Nanoparticles of Controlled Particle Size Distribution: Application of Experimental Designs," Drug Development and Industrial Pharmacy, Vol. 18, No. 10, p. 1063-1077 (1992).	
	D	CL	PHILLIPS ET AL, "Rapid Expansion from Supercritical Solutions: Application to Pharmaceutical Processes," International J. of Pharmaceutics, Vol. 94, p. 1-10 (1993).	

Examiner Signature	lvar-	Date Considered	1-18-06

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.



^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.



PTC/SB/08B (10-01)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB

Substitute for form 1449B/PTO				Complete if Known		
				Application Number	10/070.093	
INFO	RMATION	DISC	LOSURE	Filing Date	02/27/2002	
CTAT	EMENT E	V ADI	DICANT	First Named Inventor	P. York et al.	
SIMI	CIAICIAI F) I AF	LIOAN	Group Art Unit		
	(use as many s	sheets as n	ecessary)	Examiner Name	Unassigned	
Sheet	-6	of	6	Attorney Docket Number	0113.00	

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No.1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where outlished.	Τ²	
	СМ	CHANG ET AL., "Precipitation of Microsize Organic Particles from Supercritical Fluids," AIChE Journal, Vol. 35, No. 11, p. 1876-1882 (November 1989).		
d	CN	MATSON ET AL., "Rapid Expasion of Supercritical Fluid Solutions: Solute Formation of Powders, Thin Films and Fibers," Ind. Eng. Chem Res., Vol. 26, p. 2298-2306 (1987).	_	
7/h	СО	STENGERS ET AL., "Carbon Dioxide at its Critical State," Chemical & Engineering News, June 10, 1968.		
·				
		·		
Examina Signatur	4	Thurson Date Considered 16-06		

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.